Remarks

Claim 1 has been amended such that it is now commensurate with the restriction requirement. The Examiner indicated that Claims 1-5 have been found allowable.

Claims 6-15 stand rejected. Applicants have canceled Claims 6-8, 10, 11, 12, 14 and 15 without prejudice to file thereon in a continuation application.

Claim Rejections under 35 USC §112, first paragraph

1. Claim 8 was rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. Claim 8 has been canceled rendering the rejection moot.

Claims 6-8 were presumably rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. The Examiner referred to Claims 20-25 in the Office Action but no such numbered claims exist in the application. Apparently, the Examiner intended to refer to Claims 6-8 because these claims contain the term "pharmaceutical composition". If Applicants are mistaken in this belief, Applicants would appreciate further clarification regarding the rejected claims. Applicants have canceled claims 6-8 without prejudice to file thereon in a continuation application. This rejection of these claims is rendered moot.

2. Claims 9-15 were rejected as failing to comply with the enablement requirement. Applicants have canceled claims 10, 11, 12, 14 and 15. Applicants respectfully request reconsideration of the pending rejection of Claims 9 and 13.

Applicants respectfully disagree with the Examiner's objection to the specification and rejection of claims 9 and 13 for failing to provide an enabling disclosure. As the CCPA observed with respect to 35 U.S.C. §112, first paragraph.

> "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought

to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support."
In re Marzocchi, 439 F.2d 220, 223; 169 USPQ 367, 369 (CCPA 1971).

Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince a person of ordinary skill in the art of the asserted utilility of the invention. In re Bundy, 642 F.2d 430, 433; 209 USPQ 48, 51 (CCPA 1981). Furthermore, applicants submit that while the Law requires that the specification enable one skilled in the art to make and use the invention, the Law does not require exemplification, data, or tests. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance. In re Marzocchi, supra. All that is required is that the specification teach how to make and use the invention without undue experimentation. Applicants submit that this has been done.

The specification of the instant application clearly states that compounds of Formula I are particularly suitable for weight reduction (page 14, line 6) and for the treatment of excessive weight or obesity (page 14, line 18). The specification also provides a disclosure of the testing which can be used by art workers to demonstrate the effects of the agent (page 18, paragraph beginning on line 16). The doses required for administration are disclosed on page 11 in the paragraph beginning on line 10. Specific daily doses and methods of administration are within the ability of one skilled in the art to determine without undue experimentation.

The Examiner alleges that the applicant has not demonstrated sufficient guidance provided in the form of administration profiles or reference to same in the prior art. Applicants respectfully assert that that the Examiner is confusing the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. See In re Brana, supra. At 1442, quoting Scott v. Finney, 34 F. 3d 1058, 1063, 2 USPQ2d 1115, 1120 (CAFC 1994).

Moreover, it is well-established that proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utilility. As put forth by the CCPA in In re Krimmel:

> "We hold as we do because it is our firm conviction that one who has taught the public that a compound exhibits some desireable pharmaceutical property in a standard experimental animal has made a significant contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans." (Emphasis added)

In re Krimmel, 292 F.2d 948, 953; 130 USPQ 215, 219 (CCPA 1961). Furthermore, the fact that syntheses would have to be carried out and bioassays conducted in order to determine the level of activity of a given compound within the scope of the claims does not constitute "undue experimentation," particularly in an art where the level of skill is so high. In re Wands, 8 USPQ2d 1400 (CAFC 1988).

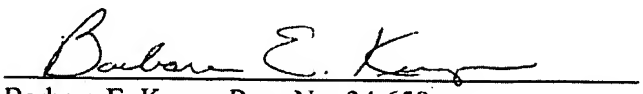
Even if applicants' specification were deficient in showing how to use the compounds as anorectic agents, the Examiner has still presented no evidence whatsoever why one of ordinary skill in the art would doubt the anorectic activity of compounds of formula I. Therefore, in the absence of a reason supplied by the Examiner to doubt the objective truth of the statements of anorectic activity made by applicants' disclosure, the Patent Office must accept the disclosure of the present application as fully enabling with respect to the use of the compounds as recited herein. Therefore, the rejection of claims 9 and 13 under 35 U.S.C. §112, first paragraph for failing to teach how to use the claimed compounds is improper and should be withdrawn.

Claim Rejections under 35 USC §112, second paragraph

Claims 6-7, 10 and 12 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have canceled Claims 6-7, 10 and 12 without prejudice to file thereon in a continuation application. This rejection is therefore rendered moot.

Applicants would welcome a telephone call from the Examiner if he believes it could resolve any outstanding issues.

Respectfully submitted,



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